



# Preparing an SBIR/STTR Application

David Beylin, MS, MBA  
NCI SBIR Development Center



**What does it take to get funded?**

- SBIR/STTRs are highly competitive
- There is a big gap between being “funded” and being “almost funded”
- **Solution:** Prepare a strong application
- Get an advantage in every possible dimension

*Deciding to Apply*



## ➤ Start-up

- Entrepreneur-founder with experience in the field
- Highly innovative technical solution to meet significant clinical need
- Significant commercial potential
- **Need feasibility data**
- Too risky for private investors

## ➤ Established small company

- Innovative new product leveraging company's expertise
- Significant commercial potential
- **Need feasibility data**
- No resources to try a new approach, but board supports SBIR

## ➤ **Chasing solicitations**

- See an NIH funding opportunity: why not apply?
- Result: distraction, lack of focus, long-term reliance on SBIRs, waste of energy

## ➤ **Chasing “cool” technologies**

## ➤ **Need cash urgently**

- SBIRs take 8 -14 months or more to get

## ➤ **Incremental upgrade to existing product**

## ➤ **“Me too” product, matching competitor’s capabilities**

## ➤ **Product is at the stage where it needs investment significantly exceeding SBIR funding levels**

# *Building the Application*

- **Highly innovative, sound, and focused science**
- **Well-designed studies**
  - **Phase I: Key feasibility question**
  - **Phase II: Proceed to eliminate technology risks**
- **Significant commercial potential**
  - **Product-focused applications**
- **Strong team and collaborators**
  - **Appropriate for the problem**
  - **Have clinicians involved: Oncologists, Pathologists, Radiologists**
  - **Other relevant scientists/professionals involved, e.g., Biostatisticians**

## Omnibus Solicitation

<http://grants.nih.gov/grants/guide/pa-files/PA-11-096.html>

<b>Funding Opportunity Title</b>	<b>PHS 2011-02 Omnibus Solicitation of the NIH, CDC, FDA and ACF for Small Business Innovation Research Grant Applications (Parent SBIR [R43/R44])</b>
<b>Activity Code</b>	<a href="#">R43/R44</a> Small Business Innovation Research (SBIR) Grant - Phase I, Phase II, and Fast-Track
<b>Announcement Type</b>	Reissue of <a href="#">PA-10-050</a>
<b>Related Notices</b>	<ul style="list-style-type: none"><li>• <a href="#">February 8, 2011</a> - See Notice NOT-AI-11-030 The purpose of this Notice is to highlight NIAID's interest in receiving grant applications to develop strategies, methods and/or tools to optimize influenza vaccine production.</li></ul>
<b>Funding Opportunity Announcement (FOA) Number</b>	<b>PA-11-096</b>

## SF 424 Application Instructions

<http://grants.nih.gov/grants/funding/424/index.htm>



U.S. Department of Health and Human Services  
Public Health Service

**SF424 (R&R)  
SBIR/STTR  
Application Guide for NIH  
and Other PHS Agencies**

A guide developed and maintained by NIH for preparing and submitting SBIR/STTR applications via Grants.gov to NIH and other PHS agencies using the SF424 (R&R)

- **Strong proposals take time to develop**
- **Seek help early in the process from:**
  - SBIR Program Staff
  - Experienced SBIR applicants
  - Academic collaborators with grant experience
  - Professional grant writers
- **Need time to fill the gaps**
  - Assemble a strong scientific team
  - Secure access to equipment and other resources
  - Obtain letters of support

- **Start informal discussions to clarify the product vision**
  - Potential customers
  - Technical experts
  - Potential investors & commercialization partners
  
- **Identify the most important technical risks**
  - Identify approaches to address those risks
  - Study design is critical

## Key #3 Build the proposal team



- **Choose the Principal Investigator (PI)**
- **Consider building a multi-PI team**
  - Allows for multidisciplinary proposals
  - Beneficial when PI lacks certain types of necessary expertise
  - Must appoint Contact PI (SBIR, > 50% of time w/ business)
- **Identify personnel who will carry out the actual work**
- **Partner to fill the gaps**
  - Academic collaborations
  - Consultants
  - Other companies
- **Use the SBIR application as engagement tool**
  - Academic researchers understand grants
  - Offer to include them on proposals as consultants/collaborators

- **Specific Aims (1 page)**
  - Focal point of the application
  - Describes the goals of the application
  - Accompanied by quantitative performance milestones
  
- **Research Strategy (Phase I: 6 pages, Phase II: 12 pages)**
  - Provide background information
  - Provide detailed technical plan to achieve the Specific Aims
  - Propose realistic scope/budget/timeline
  - Preliminary data is not required
  - ... but often powerful
  - Describe potential pitfalls and alternative angles of attack
  
- **Introduction (for resubmissions only, 1 page)**
  - Your response to reviewers' critiques

## ➤ **Other application components**

- Biosketches for all senior and key personnel (<4pages each)
- Budgets for each project period
- Separate budgets for each subcontract
- **Phase II Commercialization Plan (Phase II, 12 pages)**
- Descriptions of facilities and equipment
- Letters of support
- Human subject research section (if applicable)
- Vertebrate animals section (if applicable)
- Other information, as required

## ➤ **Grants: SF424 R&R SBIR/STTR Application Guide**

- Excellent source of administrative information
- [http://grants.nih.gov/grants/funding/424/SF424\\_RR\\_Guide\\_SBIR\\_STTR\\_Adobe\\_VerB.pdf](http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_SBIR_STTR_Adobe_VerB.pdf)

## ➤ **Contracts: see respective Request for Proposals (RFP)**

- E.g., <http://grants.nih.gov/grants/funding/SBIRContract/PHS2011-1.pdf>

- **Strongly worded letters of support from:**
  - ALL consultants and collaborators
  - Those who provide access to facilities / administrators
  - KOLs who think highly of your project
  - Customers who will buy the product once it is available
  - Current or potential industry partners
  - Current or potential investors
  - Suppliers of critical technology
  
- **A good letter of support:**
  - Explains who the writer is and why s/he is excited about the proposed project
  - Explains the writer's role in the proposal
  - Contains specific support of your story/approach

- **Who is going to review your application?**
  - Primary reviewers read your application and lead the discussion
  - All members of the Review Panel will score your application
  - Combination of academic and industry reviewers
  
- **Identify the most appropriate study section BEFORE you submit your application**
  - See CSR website for study section descriptions
  - Discuss study section selection with NCI SBIR Program Staff
  
- **What are reviewers looking for?**
  - Readable and understandable application
  - Do not assume they will know everything you know
  - Clear plan for Phase I, II, and commercialization
  - Feasible, standard methods
  - Solid letters of support

# Key #6 Run “your own” peer review



- **... before you submit**
  
- **Read your material critically, as if you were the Reviewer**
  - What are the weaknesses?
  - Point out potential difficulties, do not hide them
  - Suggest ways to address them
  
- **Ask all consultants/collaborators to review the application**
  - Act on their feedback
  
- **Recruit independent, technically trained ‘laymen’ as readers**
  - Do they understand it?
  - Are they excited?

# If you are not funded the first time...



- **Rejection is painful, but there is feedback to work with**
  - Respond to the Summary Statement carefully
  - Use peer review to improve your technology and presentation
  
- **Revise and resubmit**
  
- **Learn more about SBIR/STTR grants**
  - Talk to successful applicants
  - Explore opportunities to serve on NIH peer review panels
  - Understand the review process and dynamics

## ➤ Reviewers did not understand your proposal

➤ Reason #1: Proposal is not sufficiently clearly written

➤ Solution: Improve your presentation

➤ Reason #2: Proposal is in the wrong study section

➤ Solutions:

➤ Can you find a better study section on NIH/CSR website?

➤ [http://www.csr.nih.gov/Roster\\_proto/sbir\\_section.asp](http://www.csr.nih.gov/Roster_proto/sbir_section.asp)

➤ Discuss study section selection with the assigned NCI Program Director

- **Reviewers say the proposal is 'not innovative'**
  - Reason #1: Technology is not clearly differentiated
  - Solution: Position the technology relative to available alternatives
  
  - Reason #2: Technology is a novel combination of existing approaches
  - Solution: Emphasize novelty AND clinical need

- **Reviewers feel the team is not qualified to handle the problem**
  - Strengthen your team by adding collaborators and consultants
  - If the PI has experience gaps: put together a multi-PI team
  - Have ALL collaborators review the proposal

- **Reviewers do not think you are working on significant problem**
  - Sell them on the importance of the problem
  - Be specific and quantitative
  - Get a letter of support confirming the problem
  
- **Reviewers are critical of the approach**
  - Respond to specific criticisms
  - Revise your approach
  - Have your approach reviewed by professionals similar to the reviewers

# More Information on the NCI SBIR & STTR Website



The screenshot shows the NCI SBIR & STTR website homepage. At the top, there is a red banner with the National Cancer Institute logo and the text "National Cancer Institute" and "U.S. National Institutes of Health | www.cancer.gov". Below this is a dark blue header with the SBIR & STTR logo, navigation links for "Contact Us", "Site Map", and a search box. A light green navigation bar contains links for "About", "Funding Opportunities", "Resource Center", "News & Events", and "Success Stories". The main content area features a large banner image with the text "Leading small business innovation and commercialization in the fight against cancer". Below the banner are two main sections: "What is the NCI SBIR & STTR Program?" and "Sign up for Updates". The "What is the NCI SBIR & STTR Program?" section contains two paragraphs of text and a "Learn More" link. The "Sign up for Updates" section includes a sign-up form with a text input field for an email address and a "Go" button. To the right of these sections is a "Latest Announcements" box with a sub-section for "NCI SBIR & STTR Funding Opportunities". This box lists three grant topics: PAS-07-240, PAS-07-241, and PAS-07-242, along with their receipt dates (April 5, August 5, December 5, 2007) and a link to read more about funding opportunities. Below the announcements is a "Tips for Applying" section.

**What is the NCI SBIR & STTR Program?**

The goal of the NCI is to eliminate the suffering and death due to cancer. The Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Program is NCI's engine of innovation for developing and commercializing novel technologies and products to prevent, diagnose, and treat cancer.

The SBIR & STTR program is one of the largest sources of early-stage technology financing in the United States. We welcome entrepreneurs and small business leaders to this website to explore grant and contract funding opportunities and a new spirit of collaboration with the NCI.

[\[Learn More\]](#)

**Sign up for Updates**

Sign up to receive updates and news about the NCI SBIR & STTR Program and upcoming opportunities.

**Latest Announcements**

**NCI SBIR & STTR Funding Opportunities**

The following SBIR Grant Topics have been issued:

- [PAS-07-240](#)
- [PAS-07-241](#)
- [PAS-07-242](#)

**Receipt Dates:**  
April 5, August 5, December 5, 2007

[Read about more NCI SBIR & STTR funding opportunities.](#)

[Click here](#) to view videos from the NCI SBIR & STTR Program about how to apply for funding opportunities.

**Tips for Applying**

<http://sbir.cancer.gov>

## Questions?

**David Beylin, MS, MBA**

**Program Director**

**Phone: 301-496-0079**

**[beylind@mail.nih.gov](mailto:beylind@mail.nih.gov)**

**Sign up for updates at  
<http://sbir.cancer.gov>**